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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,128	04/12/2007	Masakazu Katsumata	46884-5485	3225
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EXAMINER HINES, JANA A				
ART UNIT 1645		PAPER NUMBER		
NOTIFICATION DATE 06/23/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbi.com  
penelope.mongelluzzo@dbi.com

**Office Action Summary****Application No.**

10/583,128

**Applicant(s)**

KATSUMATA ET AL.

**Examiner**

JaNa Hines

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 5-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Amendment Entry***

1. The amendment filed March 30, 2010 has been entered. Claims 1 and 5-17 are withdrawn from consideration. Claim 2 has been amended. Claims 2-4 and 18-25 are under consideration in this office action.

***Withdrawal of Rejections***

2. The following rejections have been withdrawn in view of applicants now pointing to support within the specification for the toxic substance assay method as claimed along with applicants amendments and arguments:

- a) The new matter rejection of claims 18-25 under 35 U.S.C. 112, first paragraph; and
- b) The rejection of claims 2-4 and 18-25 under 35 U.S.C. 112, second paragraph.

***Response to Arguments***

3. Applicant's arguments with respect to claims 2-4 and 18-25 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-4 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al., (Biochimica et Biophysica Acta. 1987. Vol. 891:22-27) in view of Wrobel et al., (J. of Fluorescence. 1998. Vol. 8, No.3:191-198).

The claims are drawn to a toxic substance assay method of assaying a toxic substance present in an aqueous solution sample to be tested, the toxic substance assay method comprising: a first step of mixing a photosynthetic sample, having a photosynthetic function, with the aqueous solution sample to prepare a test measurement solution, letting the test measurement solution stand for a predetermined standing time, and then after illuminating light onto the test measurement solution for a predetermined illumination time, measuring a light amount of a delayed fluorescence that is emitted; a second step of letting a comparison measurement solution, prepared by mixing the photosynthetic sample with a comparison sample, stand for the predetermined standing time, and then after illuminating light onto the comparison measurement solution for the predetermined illumination time, measuring a light amount of the delayed fluorescence that is emitted to thereby prepare a comparison measurement result; and a third step of computing assay values based on the light amounts of delayed fluorescence, respectively acquired in the first step and the second

step, and determining a comparison value of the assay values to assay the toxic substance present in the aqueous solution sample, wherein the assay values are temporal variations of the light amounts of delayed fluorescence acquired in the first step and the second step, and the comparison value includes curve values by determining differences of the temporal variations of the light amounts of delayed fluorescence respectively obtained from the test measurement solutions and the comparison measurement solution, and in the third step, the toxic substance present in the aqueous solution sample is assayed based on a time range in which a variation in the curve value appears and a positive or negative direction of the variation.

Schmidt et al., teach long-term delayed luminescence in blue-green algae, *Scenedesmus obliquus* and the influence of exogenous factors. Schmidt et al., teach long-term delayed luminescence for a predetermined time, varying from 0.3s up to several minutes has been studied in wild type and several pigment mutants of *Scenedesmus obliquus* during the life cycle and under the influence of various exogenous parameters such as herbicides, different pH values, temperature, preillumination and the diurnal rhythm of synchronized cells (abstract). Schmidt et al., teach the investigation of spectral and kinetic properties where complex decay kinetics as well as the comparison of excitation and emission spectra of long-term delayed luminescence with those of prompt systems associated both with PSI and PSII in long-term delayed luminescence (page 22, col.1). Schmidt et al., teach particularly a long term intermediate showing maximal luminescence after excitation with a far red light pulse was attributed to pigments of PS I (page 22, col. 1-2). Schmidt et al., teach prior

to illumination, cell suspensions were treated with inhibitors (page 22-23, col. 2-1).

Device and conditions for measuring long term delayed luminescence have been described previously described and were modified for measuring algae suspensions (page 23, col. 1). Figure 1 shows the kinetics of long-term delayed luminescence (LTDL) as a function of the development stage.

Schmidt et al., teach preirradiating light as exemplified by Figure 2D, the LTDL intermediate is strongly enhanced by irradiation with light (page 23, col. 2). Schmidt et al., teach the observation is consistent with the dependence of prompt fluorescence on the wavelength of preirradiation (page 23, col.2). Schmidt et al., teach Analysis of LTDL by treatment with various inhibitors applied immediately before the 1 s light induction or by other treatments (page 24, col. 1). Figure 2 shows both the test measurement solution and comparison measurement solution and computing assay values based on the light amount of delayed fluorescence acquired by each and determining a comparison value. Figure 2A shows dark incubation, while Figure 2F shows examples for the dependency of the kinetics of LTDL on temperature, along with concavities and convexities form curves similar to the complicated LTDL curves that have a second peak or shoulder which follows a first major decay pattern.

Schmidt et al., teach contributions of excitation ratios in LTDL decay curves. Schmidt et al., teach the induction potency for LTDL (initial rate of quantum emission) in the mutant algae by blue light, see Figure 3. Schmidt et al., teach kinetics of LTDL as a function of pH of the exogenous medium. Figure 3, shows the delayed luminescence and time after excitation. It is noted that the instant specification teach the relationship

between absorbance and delayed fluorescence, see instant Figure 37. The "delayed luminescence" referred to by Schmidt et al., is equivalent to the "curve value" recited by the instant claims.

Wrobel et al., teach time resolved delayed luminescence (DL) in the microsecond time range and the investigation of the influence of various materials (page 192, col. 2). Wrobel et al., delayed luminescence spectra on the microsecond scale time scale (page 195, col.2). The DL decay times are also different. From Figure 8 it is evident that the DL in decays much more slowly than that of other samples (page 195, col. 2). The drastically different decay kinetics reflect difference in the kinetics of the excited states responsible for the delayed process in the dyes (page 196, col. 1). Figures 9 and 10 show the delayed luminescence [counts] and the time windows. The most marked difference between the delayed luminescence and is in its decay (page 196, col.1-2).

Therefore, it would have been obvious at the time of applicants' invention to modify the toxic substance assay method of assaying a toxic substance present in an aqueous solution sample to be tested, as taught by Schmidt et al., and incorporate the comparison value includes curve values by determining differences of the temporal variations of the light amounts of delayed fluorescence respectively obtained from the test measurement solutions and the comparison measurement solution as taught by Wrobel et al., in order to provide computing assay values based on the light amount of delayed fluorescence acquired by each and determining a comparison value. Furthermore, no more than routine skill would have been required to used the aqueous solution sample is assayed based on a time range in which a variation in the curve

value appears and a positive or negative direction of the variation. Finally, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one skilled in the art at the time of the invention.

### ***Conclusion***

5. No claims allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/  
Examiner, Art Unit 1645

/Mark Navarro/  
Primary Examiner, Art Unit 1645